

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs, Network Contracting Office (NCO) 16, Station Number 502, Alexandria VA Health Care System (VAHCS), 2495 Shreveport Highway 71N, Pineville, LA 71360, on behalf of the following station:

629 Southeast Louisiana Veterans Health Care System, New Orleans, LA

2. Nature and/or Description of the Action Being Approved: On 02 Jul 13, The Contracting Office received a request to establish a firm-fixed price IDIQ contract for six (6) months to begin 01 Oct 13 through 31 Mar 14 with one (1) six month option period, to meet a continuing urgent need for Custom Sterile Surgical Packs for VISN 16s' VA Medical Centers (VAMC) and VAHCS' until new VISN or Central Region contract is awarded. This request was based on a 28 Mar 13 announcement that the VA National Acquisition Center (NAC) Federal Supply Schedule (FSS) Service would discontinue the Custom Surgical Pack Program on 01 Jun 13 (currently extended until 30 Sep 13). The Veterans Health Administration (VHA) Medical Centers and VAHCS' require short-term sole source contracts to ensure availability and consistency of products used nationwide for treatment for Veterans under the care of the Veterans Health Administration until such time as long-term contracts can be awarded. This sole source short-term contract will allow uninterrupted receipt of surgical packs while a long-term contract is being implemented. The purpose of this justification is to request sole source approval for a short term contracts with the incumbent supplier, **Alcon Laboratories**, currently providing Custom Sterile Surgical Packs for the above station. This acquisition will be procured under authority of FAR 13.5, Test Program for Certain Commercial Items. This Justification and Approval is in accordance with FAR 13.501(a) for Sole Source Acquisitions.

3. Description of Supplies/Services Required to Meet the Agency's Needs: The above stations have an urgent continuing need for custom sterile surgical packs that have been assembled from **commercial off-the-shelf** individually selected components and are customized for each facility where they are used. These packs become proprietary to the company distributing the packs. The packs are assembled by a manufacturer, sterilized, shipped to the MSPV for distribution to the health care facilities. The estimated value of this requirement for these stations is \$138,827.17 annually.

4. Statutory Authority Permitting Other than Full and Open Competition: The justification rational is based on 41 U.S.C. 253(c)(2), Unusual and Compelling Urgency. It is clinically imperative that the availability of the custom packs continue in the interim until a new VISN or Central Region contract can be awarded. Medical centers and VAHCS' employ the use of the custom packs in routine and emergency surgeries on a daily basis. These custom packs are critical to patient care and an unanticipated undersupply situation could occur unless the same number of packs remains available until a new award is made.

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority. In addition to the time required for a new manufacturer/distributor to start delivery of the custom packs needed by the individual VA facilities, there are several compelling reasons to sole source to Alcon Laboratories. These reasons included: time required to change pack manufacturers, to specify components of the custom sterile surgical packs, and identify distributors. These will take several months to implement. Alcon Laboratories is currently the only vendor which has the immediate ability to distribute the custom sterile surgical packs used and needed by these VAMCs and VAHCS's as listed in Paragraph 1 above.

Failure to establish a contract will require individual orders for these custom sterile surgical packs to be awarded through the Contracting Activity, which will not allow for just-in-time delivery. Space concerns and current VA inventory metrics do not allow for overstocking of packs. Packs are generally bulky and Logistics must keep no more than 2-4 weeks of stock on hand to meet performance measures. The process from assembly to VAHCS/VAMC delivery takes 6-8 weeks. Failure to procure custom packs on a timely basis can affect scheduled surgeries, resulting in delayed or cancelled cases and a decrease in the quality of care provided to our Veterans. The work statement requires the contractor to validate the sterilization process through the Association for Advancement of Medical Instrumentation (AAMI). Without adequate transition period to switch to a different custom sterile surgical packs manufacturer, there is a risk that this validation could not occur in time. Improperly processed custom sterile surgical packs can cause delays and under certain circumstances cause serious complications in an essential aspect of the VA's mission of providing healthcare to our Nation's Veterans.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: The Contracting Officer will ensure posting requirements to Federal Business Opportunities (FBO) are followed IAW FAR Part 13.501(a)(iii). As this is an urgent and compelling need, in order to maintain patient services in VHA medical facilities, competition amongst more than one source has been deemed impracticable by the Contracting Officer based on the considerations set out above. However, the longer term contract will be issued open market that will allow for competition to fulfill the Department of Veterans Affairs long term needs. This justification relates solely to the need of providing a bridge contract for this urgently needed requirement pending the award of the long term contract.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: Currently, the contract pricing has been established fair and reasonable per FAR 8.404(d) and will be used as a benchmark for renegotiated pricing.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: Market research was conducted concerning Custom Surgical Packs industry and it was discovered there are other providers currently in the market place. However, for the reasons stated above the urgent and compelling nature of this procurement dictates that undue delays of potentially going with one of the other manufactures overrides the possibility of competing amongst all for this limited duration sole source contract.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: Not Applicable.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: Not Applicable.

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required: The period of performance will not exceed the time necessary for the agency to enter into another contract for the required goods through the use of competitive procedures. To remove any barriers to competition in the future, prior to making subsequent acquisitions for Custom Sterile Surgical Packs, market research and competition will be sought.